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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/623,019 | 07/17/2003 | John F. Burd | DDI-0038-USA-DIV | 4593 |

7590 03/26/2007

Johnson & Johnson
International Patent Law Division
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New Brunswick, NJ 08903

| EXAMINER | |
|---|---|
| ALEXANDER, LYLE | |
| **ART UNIT** | **PAPER NUMBER** |
| 1743 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|---|---|---|
| 3 MONTHS | 03/26/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/623,019 | BURD ET AL. | |
| | Examiner | Art Unit | |
| | Lyle A. Alexander | 1743 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *20 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The preamble of claim 1 " A method for assessing the effectiveness of drug therapy..." may not be achievable by the claimed "producing a signal indicative of the concentration of the concentration of an organ marker ". The instant method does not actually measure an organ marker and cannot definitively determine effectiveness of a drug therapy. Additionally, the effectiveness of a drug therapy is much more complex system that includes individual tolerances for the drugs, other disease states that may be working against the drug therapy, etc. Clarification could be achieved by changing the preamble to read – A method for assessing conditions indicative of the effectiveness of a drug therapy ...steps of:--.

Claim 1 is not clear how the claimed "signal indicative of the concentration of the concentration of an organ marker.... a drug ... a metabolite ... " are calculated. Is there a step of comparing the test strip to a standard ? Also, it is not clear how these concentrations are displayed. Is the "display" based upon a color of the test strip ? How what steps are performed to fulfill the requirements of the preamble ? Are there comparisons of the concentrations of the plural strips that indicate an effective drug

therapy ? Finally, claim 1 requires "first", "second" and "third" body fluid samples. It is not clear if these samples are taken from the patient at the same time ?

Applicants' use different combinations from claim 1 of a-b, a-c or b-c to achieve the same results of "providing for the assessment of the subject's organ function..." . It is not clear how using these different combinations of the claimed two of the three markers will give identical results/conclusions of "the subject's organ function...". Additionally, claims 2-4 fail to further limit the subject matter of claim 1 because deletion one of the three step broadens the scope of the claims. Claims 2-4 should be deleted.

***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 3 is rejected under 35 U.S.C. 102(e) as being clearly anticipated by Cefali. See the appropriate paragraph of the 10/26/05 Office action.

In light of the above 35 USC 112 issues, the claims are best understood as a method of determining any combination of drugs; metabolites and/or organ markers. Additionally, claim 3 is improper because it fails to further limit the scope of claim 1. However, in the even Applicants' write an independent claim having the scope of claim 3, such a claim would be rejected because Cefali teach determination of the claimed drugs; metabolites and/or organ markers as "clofibrate or ibuprofen"; "glucose" and/or "AST or ALT" respectively.

Claims 1-10 and 13-14 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Tiffany et al. (USP 5,508,200).

In light of the above 35 USC 112 issues, the claims are best understood as a method of determining any combination of drugs; metabolites and/or organ markers.

Tiffany et al. teach an automated device using individual test strips/device to determine the claimed combinations of analytes. Specifically, column 13 lines 25-34 teach the claimed "phenyltoin"; "glucose or creatinine" and/or "AST or ALT or GGT".

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 11,12 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tiffany et al.

Tiffany et al. are silent to the detection of the drugs troglitazone or metformin and the metabolite fructosamine.

The court decided In re Boesch (205 USPQ 215) that optimization of a result effective variable is ordinarily within the skill of the art. A result effective variable is one that has well known and predictable results. The choice of a drug to monitor and the corresponding metabolite are results effective variables.

It would have been within the skill of the art to modify Cefali or Tiffany et al. and use the drugs troglitazone or metformin and the metabolite fructosamine as optimization of a result effective variable.

***Response to Arguments***

Applicant's arguments filed 11/14/06 have been fully considered but they are not persuasive.

Applicants' state the claims are definite because they recite various steps to determine the concentrations of various markers, drugs and metabolites. The Office maintains the above 35 USC 112 second paragraph rejections that the claims are not definite enough so that one having ordinary skill in the art would be able to make and or use the instant invention.

Applicants' state the cited prior art does not teach or suggest the claimed methods of determining drug effectiveness. In light of the above 35 USC 112 second paragraph issues, the claims are best understood as correlating the measured analyte level to a lipid profile or liver enzyme level. The Office maintains Cefali teaches determining the lipid level of the blood which is indistinguishable from that claimed.

Applicants state Cefali fails to measure the concentration of the administered drug. The Office agrees Cefali does not measure the concentration of the administered drug in the "second body fluid sample". However, claim 3 does not require the measurement of the drug and has been properly applied.

Applicants state the instant invention is directed to 3 separate test strips whereas Tiffany describes all of the tests being performed on a single substrate. The instant claims are directed to a method of applying sample to three different test strips/areas. The Office maintains Tiffany is performing and indistinguishable method of applying different samples to different test areas. Also, the instant claim language does not definitively describe the structure of the test strips sufficient to overcome the different

test areas/regions taught by Tiffany. Even if the structures of the test strips were claimed to overcome the taught test areas on a single substrate, it is not clear how convincing a structural argument would be with respect to the pending method claims. The Office maintains Tiffany is performing and indistinguishable method of applying different samples to different test areas/regions.

Applicants' traverse the 35 USC 103 rejections over Tiffany stating this reference fails to teach the claimed drugs and it would not have been within the skill of the art as optimization of a result effective variable to substitute detection of these drugs. The Office maintains the drugs in question are all well known and would be a result effective variable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lyle A Alexander
Primary Examiner
Art Unit 1743

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